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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiffs,

v.

NOVADOZ PHARMACEUTICALS LLC, MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED,

Defendants.

Civil Action No. 25-849

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION FOR A STAY OF INJUNCTION PENDING APPEAL

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Plaintiffs Novartis AG and Novartis Pharmaceuticals Corp. (together "Novartis") respectfully submit this memorandum in opposition to the Motion for a Stay of Injunction Pending Appeal ("Motion") (ECF No. 37), filed by Defendants MSN Laboratories Private Limited ("MSN Labs"), MSN Pharmaceuticals Inc. ("MSN Pharma"), and Novadoz Pharmaceuticals LLC ("Novadoz Pharma," and together with MSN Labs and MSN Pharma, "MSN" or "Defendants").

PRELIMINARY STATEMENT

The Court granted Novartis's motion for a preliminary injunction ("PI") to enjoin MSN's launch of tablets that nearly identically copy the protected trade dress of ENTRESTO®, Novartis's blockbuster heart failure medication. In reaching its decision, the Court thoroughly evaluated the PI factors and determined that each factor favored Novartis. MSN now seeks to relitigate the same factors under the guise of a motion to stay that injunction pending appeal.

MSN's Motion should be denied because it fails to raise any legitimate reason why this Court should negate the PI it just granted. There are no new facts or newly discovered law. Far from being "needed to preserve meaningful appellate review," the Motion seeks extraordinary relief that would disrupt, rather than preserve, the status quo while MSN's appeal is pending. The practical reality is that MSN is asking this Court for freedom to launch its infringing drug, so that MSN can reap the benefits of infringement while its improbable appeal is pending. Such conduct

cannot be permitted.

FACTUAL AND PROCEDURAL BACKGROUND

Novartis's ENTRESTO® medication is the number one branded heart failure treatment prescribed by physicians. (*See* Mem. of Law in Support of Order to Show Cause, ECF No. 4-1 ("Br."), at 5; Opinion, ECF No. 32 ("Opinion" or "Op."), at 1). ENTRESTO® is available in three doses, each of which comes in a unique combination of size, shape, and color (the "ENTRESTO® Trade Dresses"). (Br. at 6; Op. at 2).[1] Novartis has used the ENTRESTO® Trade Dresses exclusively for nearly a decade, and patients and healthcare providers recognize the ENTRESTO® Trade Dresses as designators of source for Novartis's life changing heart failure medication. (Br. at 19–23; Op. at 11).

On January 30, 2025, Novartis sought both a temporary restraining order ("TRO") and PI (ECF No. 4) to prevent MSN from launching generic versions of ENTRESTO® (the "MSN Drug") that nearly identically copy the ENTRESTO® Trade Dresses. The Court declined to issue a TRO but ordered expedited briefing on the motion for a PI. (*See* Jan. 31, 2025, Order, ECF No. 7).

[1] The ENTRESTO® Trade Dresses constitute the individual trade dress of each ENTRESTO® tablet as well as the three-dose trio of tablets. Each tablet has a distinct appearance: (1) the 24/26 mg tablet is a violet-white oval tablet, measuring 13.1 mm x 5.2 mm; (2) the 49/51 mg tablet is a pale yellow oval tablet, measuring 13.1 mm x 5.2 mm; (3) the 97/103 mg tablet is a light pink oval tablet, measuring 15.1 mm x 6.0 mm. (*See* Br. at 6).

After reviewing almost 100 pages of briefing, 10 fact declarations, 7 expert declarations, and close to 150 exhibits, the Court issued an Opinion and Order, granting in part and denying in part Novartis's motion for a PI. (*See* Mar. 17, 2025, Order, ECF No. 33 ("Order") and Op.). Pursuant to the Court's Order, MSN is enjoined "from manufacturing, producing, distributing, circulating, selling, marketing, offering for sale, advertising, promoting, or displaying the MSN Drug, in a manner likely to infringe on Plaintiffs' trade dress." (*See* Order at 1). In reaching its holding, the Court's Opinion considered each of the PI factors that Novartis was required to meet in support of its motion: (1) a likelihood of success on the merits; (2) irreparable harm to Novartis; (3) a balance of the parties' equities; and (4) the public interest in granting relief. (*See* Op. at 4).

In evaluating Novartis's likelihood of success on the merits, the Court concluded that the design of the ENTRESTO® tablets was protectable trade dress and held that Novartis had established a likelihood of confusion stemming from MSN's "strikingly similar" pills. (*Id*. at 3, 5–15). After finding that Novartis was likely to succeed on the merits of its claim, the Court held that "Novartis ha[d] demonstrated a likelihood of irreparable harm." (*Id.* at 18). The Court recognized that MSN's nearly identical copying of the ENTRESTO® Trade Dresses would strip Novartis of the right to control its own reputation, noting that MSN's copying of the look and feel of the ENTRESTO® tablets "puts at risk [Novartis's] reputation in the

event of a quality or safety issue with [MSN's] generic." (*Id.* at 17 (quoting *Astrazeneca AB v. Camber Pharms., Inc.*, No. 15-927, 2015 WL7307101, at *5 (D. Del. Nov. 19, 2015)) (alt. in orig.)).

Finally, in balancing the harm to MSN and public interest, the Court held that, although "[t]here is no question that MSN would suffer significant hardship if enjoined," MSN brought this injury upon itself by copying the ENTRESTO® Trade Dresses and "could have distinguished its pills." (*Id.* at 18; *see also id.* at 9). "Accordingly, on balance, a [PI] is warranted." (*Id.* at 18).

For completeness, Novartis notes some developments in ongoing patent litigation between the parties. At the time this Court's injunction was entered, MSN was also subject to an injunction issued by the U.S. Court of Appeals for the Federal Circuit in *Novartis Pharmaceuticals Corp. v. Torrent Pharma, Inc.*, Appeal No. 23-2218 (Fed. Cir.) ("Patent Litigation") that prohibited MSN from launching its product. (Order Granting Inj., Patent Litigation, ECF No. 127).

On March 25, 2025, the Federal Circuit issued a decision in the Patent Litigation, denying MSN's petitions for rehearing of rulings validating certain of Novartis's patent rights and related marketing exclusivity. (Order Den. Pet. For Reh'g, Patent Litigation, ECF No. 157). On April 1, 2025, the Federal Circuit issued a mandate sending the Patent Litigation back to the U.S. District Court for the District of Delaware (Mandate, *In re Entresto (Sacubitril/Valsartan) Patent*

Litigation, No. 20 md 2930 (D. Del.) ("*In re Entresto*"), ECF No. 1823), at which time the Federal Circuit's injunction automatically ended. Given the Federal Circuit's validation of Novartis's patent rights, the district court immediately entered a final judgment (1) directing the FDA to reset the effective approval date of MSN's abbreviated new drug application ("ANDA") to a date no earlier than July 16, 2025, "the date after the expiration of pediatric exclusivity awarded to Novartis…," and (2) enjoining MSN from launching its drug in the meantime. (Final J., *In re Entresto*, ECF No. 1824 ("Final Judgment")).

Despite this Final Judgment, the parties' disputes remain unresolved, as MSN has now filed multiple motions regarding the impact and scope of Novartis's patent rights. For example, on April 29, 2025, the Delaware District Court will hear oral argument on MSN's motion to delist one of Novartis's patents. If the court grants that motion, Novartis could lose the pediatric exclusivity that is the basis of the Final Judgment's injunction. This leaves open the possibility that this Court's injunction may become the only restraint prohibiting MSN from launching its infringing drug. (Oral Order, *In re Entresto*, ECF No. 1825).

LEGAL STANDARD

In this Circuit, "a motion for a stay pending appeal . . . is an extraordinary remedy," and "[s]uch stays are rarely granted." *Conestoga Wood Specialties Corp. v. Sec'y of U.S. Dep't of Health & Hum. Servs.*, No. 13-1144, 2013 WL 1277419, at

*1 (3d Cir. Feb. 8, 2013) (denying plaintiffs' motion for stay pending appeal); *see also HR Staffing Consultants, LLC v. Butts*, No. 15-3155, 2015 WL 3561618, at *2 (D.N.J. June 4, 2015) (denying defendant's motion for stay pending appeal); *Robinson v. Murphy*, No. 20-5420, 2020 WL 13891018, at *1 (D.N.J. Oct. 28, 2020) (denying plaintiffs' motion to obtain an injunction pending appeal).

The standard for a motion for a stay pending appeal is "essentially the same as that for obtaining a [PI]"—the moving party must show:

> (1) a likelihood of success on the merits; (2) that it will suffer irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to the nonmoving party; and (4) that the public interest favors such relief.

Conestoga Wood Specialties, 2013 WL 1277419, at *1 (quoting *Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004)). In evaluating the likelihood of success on the merits of appeal, the Third Circuit will review the district court's "findings of fact for clear error" and assess its legal conclusions "de novo." *HR Staffing Consultants*, 2015 WL 3561618, at *2.

Contrary to MSN's suggestion, the four factors are not treated equally. While the Court "must balance and 'consider the relative strength of the four factors[,]' . . . [i]f a movant fails to make the requisite showing on either of the first two factors, 'the stay should be denied without further analysis.'" *Corp. Synergies Grp., LLC v. Andrews*, No. 18-13381, 2019 WL 2743791, at *1 (D.N.J. Jan. 9, 2019) (quoting *In re Revel AC, Inc.*, 802 F.3d 558, 568, 571 (3d Cir. 2015)); *see also Reilly v. City of*

Harrisburg, 858 F.3d 173, 177 n.2, 179 (3d Cir. 2017) (in the "stay-pending-appeal context," a movant "must meet the threshold for the first two 'most critical' factors").

While these factors are similar to those considered in evaluating a motion for a PI, "[a] motion for stay pending appeal is not a second bite at the [PI] apple." *Boynes v. Limetree Bay Ventures, LLC*, No. 21-0253, 2023 WL 5221539, at *2 (D.V.I. Aug. 14, 2023). Accordingly, "a motion for stay pending appeal of a granted [PI] is properly denied where a party's motion to stay merely re-raises the same arguments the Court already decided in the course of issuing the underlying [PI]." *Id*.

ARGUMENT

MSN has not met the "very heavy burden of persuasion" required to justify a stay of the Court's injunction. *See F.T.C. v. Equitable Res., Inc.*, No. 07-0490, 2007 WL 1500046, at *1 (W.D. Pa. May 21, 2007).

I. MSN Has Failed to Provide Legal Support for the Extraordinary Relief It Seeks.

MSN has failed to cite a single case in which a court has granted the extraordinary relief MSN seeks here: a stay that negates a *prohibitory* PI that the court just granted. *See HR Staffing Consultants*, 2015 WL 3561618, at *2 (denying motion to stay that "effectively ask[ed] the court to negate the [PI] it just granted"). This relief is particularly extraordinary because rather than "a mere preservation of some neutral status quo," it is "tantamount to victory" for the moving party. *Id*.; *cf*.

In re Broadstripe, LLC, No. 09-10006, 2009 WL 774401, at *4 (D. Del. Mar. 26, 2009) (granting stay preserving the parties' positions pending appeal where the bankruptcy court's "mandatory" PI "alter[ed] the status quo").

Here, MSN does not seek to preserve the status quo—a state in which MSN has not yet launched its product and its infringement is merely imminent. Instead, MSN seeks relief that would enable it to alter the current state of play by launching its infringing product and has expressed its clear intent to do so in any window where no court injunction is in effect. (Decl. of David Lossignol in Support of Pls.' Motion, ECF No. 4-6 ("Lossignol Decl."), ¶ 18 (describing an email from MSN's counsel indicating an intent to launch once no injunction is in place)).

Despite MSN's assertions to the contrary (Motion at 28–29), MSN is not entitled to any first-mover advantage. As explained above, although MSN continues to challenge Novartis's patent rights, the recently-entered Final Judgment in the Patent Litigation held that MSN's filing of its ANDA for the MSN Drug infringed certain of Novartis's patent rights—making clear that MSN currently has no right to launch and should not have been approved by the FDA before the end of Novartis's patent and marketing exclusivity rights. Even if MSN had rights to a first-mover advantage, MSN has cited no evidence demonstrating that this Court's PI would deprive MSN of its advantage over Noratech, the other potential generic sacubitril/valsartan manufacturer cited by MSN. (*Id.* at 28). Noratech has not yet

received FDA approval for its generic product, which is required before it can launch. In addition, Noratech cannot receive such approval during the marketing exclusivity period associated with Novartis's patent rights for ENTRESTO® (spanning from January 16, 2025 through and including July 15, 2025).

In addition, the Motion cites only two cases involving a motion to stay[2]—neither of which seeks the type of relief MSN requests. Both cases involved stays of orders (not injunctions) that authorized action—rather than prohibited it—such that a stay was needed to preserve the status quo pending appeal. *See In re Revel AC*, 802 F.3d at 575 (reversing in part bankruptcy court's denial of stay so that casino owner could not sell casino free and clear of tenant's lease while action was pending); *Nken v. Holder*, 556 U.S. 418, 436 (2009) (vacating and remanding denial of motion to stay a removal order in an immigration case so that appellant could remain in the United States pending adjudication of a petition for rehearing). These cases are a far cry from MSN's extraordinary request for a stay that would allow it to alter the status quo by launching its infringing generic during any window it is not subject to a restraint.

II. MSN Has Not Shown a Likelihood of Success on Appeal.

Even setting aside the extreme nature of the relief MSN requests, the Motion

[2] MSN primarily cites to opinions addressing motions for PI, which underscores its inappropriate efforts to relitigate the very motion it lost.

should fail because it is merely a repackaging of the arguments MSN presented in opposition to Novartis's motion for a PI. The Court should follow common practice in this Circuit by adopting its prior reasoning and denying MSN's "second bite." *See HR Staffing Consultants*, 2015 WL 3561618, at *2 ("Because the stay that defendant seeks is simply the other side of the [PI] coin, [the court] need not write at length. The reasons for denying a stay are those set forth in [the court's] opinion granting the [PI]."); *Corp. Synergies Grp.*, 2019 WL 2743791, at *2 (denying stay and "incorporat[ing] the reasoning set forth" in its prior decision granting PI); *Robinson*, 2020 WL 13891018, at *2 (denying a motion to obtain an injunction pending appeal and incorporating the same reasons set out in the court's prior opinion "as the facts before it remain largely the same at this juncture").

A. The Court Properly Held That Novartis Demonstrated Irreparable Harm.

MSN's Motion both impermissibly recycles prior irreparable harm arguments that this Court rejected and raises an entirely new argument that it could have made prior to the Court's ruling. *See Boynes*, 2023 WL 5221539, at *2 (denying motion for stay pending appeal of granted PI where the movant merely re-raised prior arguments); *see also Int'l Bhd. of Teamsters, Loc. 211 v. PG Publ'g Co.*, No. 19-1472, 2019 WL 9101872, at *1 (W.D. Pa. Dec. 27, 2019) (rejecting new arguments and evidence which could have been raised "when the parties litigated the motion for a PI in the first place"). Specifically, MSN contends that this Court's holding on

irreparable harm was in error because "Novartis's multi-year delay in bringing this action militates against injunctive relief and that its reputational harm theory is too speculative." (Mem. of Law in Opp'n to Pls.' Order to Show Cause, ECF No. 13 ("Opp'n"), at 34–35; *see also* Motion at 9–17). In addition, for the first time, MSN contends that the sophistication of consumers should rebut any presumption of irreparable harm. (*See* Motion at 9). There is no merit to any of these arguments.

1. The Court's Legal Framework Favored MSN.

As a threshold matter, MSN suggests that the Court's application of the burden shifting framework for irreparable harm under the Lanham Act creates a legal error that will favor it on appeal. (*See Id*. at 8). While Novartis agrees that Novartis was entitled to a presumption of irreparable harm following the Court's conclusion that it was likely to succeed on the merits of its trade dress infringement claim, such a presumption would only *help* Novartis, not hurt it. *See Sidewinder Films, LLC v. Sidewinder Films, LLC*, No. 19-13992, 2022 WL 6964829, at *4, *6 (D.N.J. Oct. 11, 2022) (the Trademark Modernization Act of 2020 ("TMA") entitles plaintiffs seeking injunctive relief to a rebuttable presumption of irreparable harm upon finding a violation of the Lanham Act); *see also* 4 McCarthy on Trademarks and Unfair Competition § 30:47 (5th ed.) ("McCarthy on Trademarks") (following the TMA, "there is no doubt that the presumption will lessen the burden on a trademark owner who seeks a [PI]").

MSN's assertion that it could have rebutted any presumption of harm to which Novartis was entitled (*see* Motion at 8–9) is purely academic because this Court held Novartis to a higher standard; rather than rely on any presumption, the Court held that Novartis *demonstrated* it was likely to be irreparably harmed. (*See* Op. at 15, 18 (requiring Novartis to "demonstrate that [it] is likely to suffer irreparable harm if an injunction is not granted" (quoting *Ferring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 217 (3d Cir. 2014)))). Novartis met that higher standard—the very same standard Novartis would have needed to meet had MSN rebutted any presumption of irreparable harm. So, reference to any allegedly incorrect application of the burden shifting framework can be disregarded here.

2. The Court's Finding of Irreparable Harm Was Supported by Facts and the Law.

Based on its review of the PI record, the Court held that Novartis established a likelihood of irreparable harm. (*Id*. at 15–18). MSN's restatement of previously rejected arguments that reputational harm to Novartis is merely theoretical or speculative does not undermine the Court's holding. (*See* Motion at 9–14); s*ee also Nat'l Shooting Sports Found. v. Platkin*, No. 22-6646, 2023 WL 2344635, at *1 (D.N.J. Mar. 3, 2023) (denying motion for a stay when it would "arguably be tantamount to a reconsideration and reversal of the Court's own [prior] decision"); *Robinson*, 2020 WL 13891018, at *2 (denying a motion to obtain an injunction pending appeal and "incorporating [the] reasoning set out" in prior opinion and

order). The Court was right to reject these arguments when MSN raised them in opposition to Novartis's motion for a PI (*see* Section III, Opp'n at 35 and Op. at 17 (acknowledging this argument)), and the Court should do so again here.

This Court's express holding that "Novartis has *demonstrated* a likelihood of irreparable harm" was amply supported by record evidence. (*See* Op. at 17–18 ("find[ing] the holding in *Astrazeneca* persuasive, that a misplaced affiliation with Novartis (and ENTRESTO®) 'puts at risk [Novartis's] reputation in the event of quality or safety issues with [MSN's] generic'")). For example, Novartis's briefing and supporting declarations included:

- Evidence showing Novartis has cultivated a reputation for high-quality treatments, with ENTRESTO® acting as a "key reputation driver" for Novartis. (Decl. of Kristin Miller in Support of Pls.' Motion, ECF. No. 4-3, ¶¶ 17, 21 ("consumers and physicians know they can trust Novartis to provide high quality treatments"; doctors surveyed in a 2024 ZoomRx study "noted Novartis's 'patient commitment and engagement'" and "called out ENTRESTO® as a '*key reputation driver*' for Novartis")).

- Evidence that medical professionals—who "are not immune to confusion and medical error…often rooted in confusing packaging, labeling or copycat drugs"—can inadvertently confuse the MSN Drug and ENTRESTO®, and their corresponding prescribing information, based on the nearly identical appearance of the products, resulting in dosing errors. (*See* Decl. of Dr. Arash Nayeri in Support of Pls.' Motion, ECF No. 4-11 ("Nayeri Decl."), ¶¶ 29(c), 40–50).

- Evidence that confused medical professionals, believing the MSN Drug is ENTRESTO® or mistakenly referring to the MSN Drug's label when prescribing ENTRESTO®, will attribute issues with the MSN Drug to Novartis and ENTRESTO®, impairing their reputation and goodwill. (*See* Brief at 37–38). This harm is likely because:

- Generic medicines "may not always result in the same clinical outcomes" as their branded counterparts. (Nayeri Rebuttal Decl. ECF No. 17-1 ("Nayeri Reb. Decl."), ¶ 8(a)).

- Generic medicines can have different negative side effects, including those triggered by different inactive ingredients found in generics versus their branded counterparts "to which some patients may have sensitives or intolerances." (*Id*. at ¶¶ 11–12).

- Errors in prescribing by medical professionals relying on MSN's label who fail to follow the reduced dosing regimen in ENTRESTO®'s prescribing information can have negative side effects. (Nayeri Decl. ¶¶ 46–50).

This and other record evidence supports a finding of irreparable harm. *See Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 205 (3d Cir. 2014) (finding irreparable harm based on "fair inferences from facts in the record").[3]

Further supporting Novartis are the many cases that found irreparable harm would arise from a loss of control over reputation, without evidence of actual

[3] This stands in contrast to the cases cited by MSN where the PI movants provided no evidence of harm—*see Del. State Sportsmen's Ass'n, Inc. v. Del. Dep't of Safety and Homeland Sec.*, 108 F.4th 194, 198 (3d Cir. 2024) (movants "offered no details about how they would be harmed"); *Nichino Am., Inc. v. Valent U.S.A. LLC*, 44 F.4th 180, 187 (3d Cir. 2022) (same); *Tristar Prods., Inc. v. E. Mishan & Sons, Inc.*, No. 17-1204, 2017 WL 1404315, at *13–14 (D.N.J. Apr. 19, 2017) (same)—or provided evidence that was found to be unpersuasive, *see 7-Eleven, Inc. v. Sodhi*, No. 13-3715, 2016 WL 541135, at *6 (D.N.J. Feb. 9, 2016) (no irreparable harm where plaintiff relied on seven complaints from one of several locations owned by defendant franchisee, many of which occurred prior to relevant period, and "there [was] no way of knowing whether these sorts of complaints have occurred at other [plaintiff's] stores nationwide"); *Atari Interactive, Inc. v. Printify, Inc.*, 714 F. Supp. 3d 225, 238 (S.D.N.Y. 2024) (plaintiff's "evidence of [alleged] harm consists entirely of a few conclusory paragraphs in [a] declaration").

confusion or an inferior product. *See, e.g.*, *Groupe SEB USA*, 774 F.3d at 205 (finding irreparable harm because "harm to reputation and goodwill constitutes irreparable harm, so long as the plaintiff makes a clear showing"); *MarbleLife, Inc. v. Stone Res., Inc.*, 759 F. Supp. 2d 552, 563 (E.D. Pa. 2010) (finding irreparable harm without evidence defendant's business was inferior, given plaintiff's loss of control over its reputation); *OTR Wheel Eng'g, Inc. v. W. Worldwide Servs., Inc.*, 602 F. App'x 669, 672 (9th Cir. 2015) (finding irreparable harm because "[l]oss of control over business reputation and damage to goodwill are cognizable irreparable harms in the trademark infringement context" even where "reputational injury was not based on any evidence that [defendant's product] was an inferior product").

MSN's insistence that Novartis was required to submit "evidence that MSN's product was lower quality, or that there was actual confusion in the marketplace, or that MSN was attempting in bad faith to create such confusion," (Motion at 11), is not only incorrect but would undermine the entire purpose of preliminary relief. It is axiomatic that "[i]f the threatened infringing acts of defendant are approaching and about to occur, then injunctive relief may be obtained even before defendant actually opens for business. A trademark owner does not have to await the impact of the threatened infringement to obtain preventive relief." 4 McCarthy on Trademarks § 30:10. If the Court were to hold Novartis to MSN's standard, no PI

could issue before a product has launched—and by then it would be too late.[4] In addition, though the Court declined to find bad faith based merely on awareness of Novartis's trade dresses, looking at the totality of evidence, it found that "MSN intended for the pills to look similar." (Op. at 14). That intention underscores the need to prevent any infringing sales of MSN's confusingly similar products.

3. This Court Considered, But Rejected, MSN's Reliance on *Becerra*.

Likewise, the Court should not entertain MSN's continued insistence that *Novartis Pharmaceuticals Corp. v. Becerra*, No. 24-02234, 2024 WL 3823270 (D.D.C. Aug. 13, 2024), requires the Court to find that there is no likelihood of irreparable harm to Novartis. This Court considered *Becerra* and declined to follow it because "that case involved FDA's approval of the MSN Drug." (Op. at 17). In doing so, the Court had before it MSN's contention that "[t]his Court should follow the D.C. court's reasoned analysis" on the question of reputational harm. (*See* Opp'n at 35). This Court's reasoned decision not to follow the *Becerra* holding—upon

[4] This procedural posture further distinguishes MSN's cited cases in which the alleged infringement had already begun but had not resulted in evidence of harm. *See Buzz Bee Toys, Inc. v. Swimways Corp.*, 20 F. Supp. 3d 483, 513 (D.N.J. 2014) (defendant had launched its infringing products, yet plaintiff failed to "show[] that any consumers blame[d] [it] for or associate [it] with [defendants'] product failures, if any"); *Tristar Prods., Inc.*, 2017 WL 1404315, at *13–14 (defendant had launched its infringing products yet there was no evidence of harm); *Atari Interactive, Inc.*, 714 F. Supp. 3d at 238 (same); *Kohler Co. v. Bold Int'l FZCO*, 422 F. Supp. 3d 681, 707 (E.D.N.Y. 2018) (same). Here, infringement is imminent but has not yet begun.

consideration of MSN's argument—does not constitute any error. *Becerra* is not binding precedent on this Court; it involves different factual and expert evidence than that presented here; and it dealt with regulatory rights as opposed to the trade dress rights at issue here. Moreover, this Motion is not the appropriate means for MSN to relitigate its previously rejected argument. *See Int'l Bhd. of Teamsters, Loc. 211*, 2019 WL 9101872, at *2 ("[A] motion to stay should not be used to relitigate matters, submit new evidence, or 'raise arguments which could, and should, have been made before the judgment issued,'" (internal citation omitted)).

4. MSN's Efforts to Argue Novartis Has Not Established Loss of Market Share Are Inapposite.

MSN's argument that Novartis presented no evidence it would lose market share, (Motion at 14), is irrelevant. The Court did not conclude that Novartis would lose market share or otherwise base its finding of irreparable harm to Novartis on lost market share. (*See* Op. at 17). Nor did the Court need to do so. Loss of market share and reputational harm are distinct harms, and Novartis does not need to show loss of market share for the Court to properly find irreparable harm. *See GlaxoSmithKline LLC v. Boehringer Ingelheim Pharms., Inc.*, 484 F. Supp. 3d 207, 227–28 (E.D. Pa. 2020) (finding irreparable harm to plaintiff's reputation and goodwill, despite no loss in market share); *Everett Lab'ys, Inc. v. Breckenridge Pharm., Inc.*, 573 F. Supp. 2d 855, 867–69 (D.N.J. 2008) (loss of market share and

loss of goodwill are two separate forms of irreparable harm).[5]

MSN's market-share argument should be rejected for the separate reason that it is lifted nearly word-for-word from MSN's opposition brief, (*compare* Opp'n at 35–36 *with* Motion at 14), making consideration here even more inappropriate. *See Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms.*, No. 00-5361, 2001 WL 493266, at *1 (D.N.J. Jan. 17, 2001) ("[Defendant] offers no new circumstances to support its application for a stay []. Therefore, granting [the] motion for stay would effectively be a reconsideration and reversal of the Court's [earlier] decision.").

5. The Court Properly Held That the Delay Alleged by MSN "Does Not Vitiate Irreparable Harm."

In opposing Novartis's motion for a PI, MSN argued that Novartis improperly delayed in seeking the PI. (*See* Opp'n at 1–2, 33–34). Having failed to persuade the Court the first time, MSN makes the exact same arguments again on this Motion. (*Compare* Motion at 15–16 *with* Opp'n at 33–34). Here, MSN's arguments only highlight that earlier disclosures of its pills in 2020 and 2021 were "under the terms of [a] protective order" in related patent litigation (Motion at 16), and that Novartis filed suit once it had enough information to confirm that MSN intended to infringe

[5] Even though evidence of lost market share is not required to deny MSN's Motion, Novartis is likely to suffer lost market share given how "strikingly similar" the MSN Drug is, (Op. at 3), and, in the event of any issues with the MSN Drug, reputational blowback is likely to flow, at least in part, to Novartis.

Novartis's protected trade dress. Based on these facts, the Court held that "given the complexities of this case and the fact that the MSN Drug has not yet gone to market," Novartis's delay did not preclude a finding of irreparable harm. (Op. at 17). MSN's second "bite at the [PI] apple" should be rejected. *See Boynes*, 2023 WL 5221539, at *2.

a. *MSN's Protective Order Arguments Constitute Re-litigation of Rejected Positions.*

MSN's contention that Novartis should have breached a protective order to file this litigation earlier remains unavailing, and this Court should reject this argument for the same reasons it did so in its Opinion. (*See* Op. at 15–17).

MSN's argument that Novartis should have "[sought] a carve-out from the protective order or challeng[ed] the confidentiality of the images of MSN's pills"[6] (*see* Motion at 16), is equally meritless. The facts here are distinct from the singular case MSN cites to support this theory. In *Cambridge Literary Properties, Ltd. v. W. Goebel Porzellanfabrik G.m.b.H. & Co. Kg.*, 448 F. Supp. 2d 244, 264 (D. Mass. 2006), *aff'd*, 510 F.3d 77 (1st Cir. 2007), the court rejected plaintiff's argument that

[6] To the extent this Court views MSN's contention that Novartis should have sought a carveout from the protective order as distinct from MSN's previously rejected arguments, this argument is new and should be disregarded. MSN was aware of the protective order, could have raised this argument for the Court's consideration in its opposition to Novartis's motion for a PI, but chose not to do so. *See Int'l Bhd. of Teamsters, Loc. 211*, 2019 WL 9101872, at *1–3 (rejecting new arguments that could have been raised during briefing on the motion for a PI).

the statute of limitations should be tolled due to a protective order in a prior litigation that "prevented [it] from using or disclosing its knowledge" because (1) plaintiff's counsel was also one of the attorneys of record in the earlier suit, who the record did not establish was prevented from accessing the protected facts, and (2) plaintiff had enough facts in hand to initiate litigation. *Id.* The same is not true for Novartis: (1) current counsel did not have access to the facts covered by the protective order, (Reply at 11–12; Decl. of Daniel M. Silver in Support of Pls.' Reply, ECF No. 17-3 ("Silver Decl."), ¶¶ 30-31), and (2) Novartis did not independently have the publicly or otherwise available facts it needed to initiate litigation based on a good faith investigation, until it acted to initiate this case.

b. *As This Court Previously Held, Novartis's Five-Month Delay Was Justified.*

MSN's contentions that Novartis's delay of five months was unjustified and therefore negates Novartis's showing of irreparable harm, (Motion at 16–17), are yet another attempt to relitigate arguments this Court rejected. (*See* Op. at 15–17).

Novartis provided an explanation for why it did not immediately file suit following the disclosure of MSN's trade dress in August 2024, which the Court agreed was the earliest Novartis could have learned about the MSN Drug's appearance for purposes of *this* case. (*Id.* at 16). Despite seeing the written description and image of the MSN Drug in its ANDA, Novartis had no proof at that time that the MSN Drug would actually launch in that format. (*See* Lossignol Decl.

¶ 14 ("ANDA images can be altered and are not always representative of the look and feel of a product in real life."); Brief at 11). Novartis waited to sue until it had additional proof and appropriate certainty regarding the MSN Drug's packaging and the timing of MSN's launch. (*Id.*).

Novartis's actions are the same type of good faith efforts to investigate that courts have consistently found justify delays of even longer than five months. *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 129 F. Supp. 2d 351, 368 (D.N.J. 2000), *aff'd but criticized on different grounds*, 290 F.3d 578 (3d Cir. 2002) (seven-month delay caused by good faith efforts to investigate the facts and pursue remedies outside of litigation does not undermine claim of irreparable harm); *Sunquest Info. Sys., Inc. v. Park City Sols., Inc.*, 130 F. Supp. 2d 680, 698 (W.D. Pa. 2000) (delay of over a year does not rebut the presumption of irreparable harm since plaintiff had to investigate the scope and severity of the trademark infringement); *Fisher-Price, Inc. v. Well-Made Toy Mfg. Corp.*, 25 F.3d 119, 125 (2d Cir. 1994) (six-month delay was reasonable because plaintiff was investigating and determining the extent of infringement).

Novartis's explanation for waiting until an appropriate time to file this litigation makes this case readily distinguishable from the cases cited by MSN. *See New Dana Perfumes Corp. v. Disney Store, Inc.*, 131 F. Supp. 2d 616, 630 (M.D. Pa. 2001) (no irreparable harm where plaintiff's five-month delay was

"unexplained"); *Ultimate Trading Corp. v. Daus*, No. 07-4203, 2007 WL 3025681, at *3 (D.N.J. Oct. 15, 2007) ("Plaintiff fails to provide any explanation, whatsoever, for this delay."); *Del. State Sportsmen's Ass'n*, 108 F.4th at 205–06 (finding no likelihood of irreparable harm because "[t]he challengers have shown no harms beyond ones that can be cured after final judgment" and only considering delay as part of overall balancing of the equities analysis); *Equibal, Inc. v. 365 Sun LLC*, No. 21-6254, 2024 WL 1526178, at *10 (S.D.N.Y. Apr. 9, 2024) (unexplained four-month delay prior to filing motion for PI defeated presumption of irreparable harm, but four-month delay prior to filing complaint attributed to "good-faith attempts to investigate"); *Two Hands IP LLC v. Two Hands Am., Inc.*, 563 F. Supp. 3d 290, 300 (S.D.N.Y. 2021) (failure to provide "any persuasive justification" for delay precluded finding of irreparable harm). If anything, these cases demonstrate that assessments of delay require a fact-specific analysis of the record—an analysis this Court properly conducted in issuing its Opinion. (*See* Op. at 15–17).

6. MSN's Contention That Consumer Sophistication Rebuts Irreparable Harm Is an Entirely New Argument That Should Be Disregarded.

MSN newly argues that the sophistication of ENTRESTO® consumers rebuts any presumption of irreparable harm to which Novartis is entitled. (Motion at 9). This should be rejected because new arguments are not appropriate in connection with a motion to stay. *See Int'l Bhd. of Teamsters, Loc. 211*, 2019 WL 9101872, at *2. While MSN argued that delay should rebut any presumption of irreparable harm

in connection with its opposition to Novartis's motion for a PI, (Opp'n at 33), it made no such irreparable harm arguments with respect to consumer sophistication in its opposition, (*see id*. at 32–36). Accordingly, MSN cannot rely on this new argument now and, in any event, Novartis has provided sufficient evidence to establish a likelihood of irreparable harm stemming from MSN's offering of a nearly identical product likely to confuse consumers.[7] *See* Section II(A)(2) *supra*.

B. The Court Properly Held That Novartis Demonstrated a Likelihood of Success on Its Trade Dress Claim.

1. The Court Correctly Analyzed Functionality.

Contrary to MSN's claims, the Court did not apply the "incorrect standard" for functionality or err by failing to apply "controlling precedent in *Shire US Inc. v. Barr Lab'ys, Inc.*, 329 F. 3d 348 (3d Cir. 2003)." (Motion at 17–21). Through each of these arguments, MSN seeks to relitigate the Court's PI Opinion, which again is inappropriate at this stage. *See Boynes*, 2023 WL 5221539, at *2; *Int'l Bhd. of*

[7] MSN's reliance on *Nichino America, Inc. v. Valent U.S.A. LLC* is misplaced. In that case, the plaintiff, which sold a solid-form pesticide under the mark CENTAUR, failed to provide any evidence that it would be harmed by defendant's sale of a liquid-form pesticide under the mark SENSTAR, after "narrowly demonstrat[ing] its infringement claim would likely succeed." 44 F.4th at 183–84. The plaintiff did not even dispute that it had failed to provide such evidence. *Id*. at 187. In contrast, Novartis has soundly demonstrated its infringement claim is likely to succeed and has provided ample evidence of irreparable harm, *see* Section II(A)(2) *supra*.

Teamsters Loc. 211, 2019 WL 9101872, at *2. Moreover, neither is an argument on which MSN can reasonably expect to prevail before the Third Circuit.

a. *MSN's Analysis of This Court's Legal Conclusions Is Misleading.*

In finding that "Novartis has met its burden in demonstrating that the trade dress is likely not functional," (Op. at 10), the Court recognized that "[a] nonfunctional feature is one that 'is unrelated to the consumer demand . . . and serves merely to identify the source of the product or business'"; whereas "a functional feature is 'one that is essential to the use or purpose of the article, affects the cost or quality of the article, or one that, if kept from competitors, would put them at a significant non-reputation-related disadvantage,'" (*id.* at 5–6 (quoting *EBIN New York, Inc. v. Kiss Nail Prods., Inc.*, No. 23-2369, 2024 WL 1328029, at *6 (D.N.J. Mar. 28, 2024))). MSN inaccurately frames this Court's applications of this standard in a vain attempt to find errors where none exist.

First, this Court did not "impermissibly f[ind] against MSN because it purportedly had 'alternatives.'"[8] (Motion at 3). Its finding that MSN could have chosen different colors, shapes, or sizes (*see* Op. at 9) was merely a recognition that those features, together, do not serve a functional purpose for the ENTRESTO® Trade Dresses. As the Court explained in rejecting MSN's theory of functionality,

[8] In fact, this word appears nowhere in the Court's analysis of functionality.

"[t]he functionality doctrine cannot stand for the broader proposition that any distinctive look and feel of a pill means generic brands are free to wholesale copy them under the guise of ensuring patients, whose medication is prescribed by doctors, know what they are taking." (*Id.*). Because these features lack functionality, MSN could have chosen from nearly 20 million possibilities of feature combinations—it was not required to copy the ENTRESTO® Trade Dresses.

This is entirely in line with *Ezaki Glico Kabushiki Kaisha v. Lotte International America Corp.*, 986 F.3d 250 (3d Cir. 2021), *as amended* (Mar. 10, 2021), which recognized that "design features" of a functional article can still be non-functional. *Id.* at 257. In other words, "[t]he question is not whether the product or feature is useful, but whether 'the particular shape and form' chosen for that feature is." *Id.* (quoting 1 McCarthy on Trademarks § 7:70). The Third Circuit further explained that "ironing-board pads need 'to use *some* color . . . to avoid noticeable stains,' [but] there is no functional reason to use green-gold in particular." *Id.* (quoting *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 66 (1995)). Likewise, producers of sacubitril/valsartan tablets may decide to use *some* color to distinguish doses (although even this is unnecessary); however, there is no functional reason to use the colors of white-violet, light yellow, and light pink, (and in that sequence), as those particular colors do not confer an "edge in usefulness." *Id.*; (*see also* Op. at 9 ("Simply put, MSN could have just picked different colors.")).

Second, MSN further distorts the Court's findings to create the impression that the Court applied an incorrect standard. For example, MSN misconstrues the Court's acknowledgment of Dr. Mark Robbins' opinions. (Motion at 18). The Court recognized Dr. Robbins' views that "drug shape and color can be helpful for patients to identify their prescriptions" because they identify the *brand* of a prescribed medication. (Op. at 7–8). This is why he opined that "a noticeable change in pill appearance is an important signal to patients that their medication is being switched." (*Id.* at 8 (citing Decl. of Dr. Mark Robbins in Support of Pls.' Motion, ECF No. 4-10 ("Robbins Decl."), ¶ 18)).[9] He did not opine, as MSN claims, that ENTRESTO®'s appearance "has an element of functionality." (Motion at 18). Nor was this "a factual finding that the Entresto trade dress is 'useful,' and thus functional under *Ezaki Glico*." (*Id.*).

Third, MSN points to generalized statements about medications to suggest that the ENTRESTO® Trade Dresses are functional. This Court's mention of the appearance of medications generally—not specifically on the ENTRESTO® Trade

[9] In his rebuttal declaration, Dr. Mark Robbins explained: "my use of the language 'help identify which medication to take' refers to patients relying on pill appearance to know that they are taking Entresto (i.e., the medication that they have been prescribed and have been taking for chronic heart failure). In other words, this relates to patients identifying that their medication continues to be from the same source that it has been from in the past, i.e., the maker of Entresto (whether patients recognize that maker as Novartis or not)." (Dr. Mark Robbins Rebuttal Decl., ECF No. 17-2 ("Robbins Reb. Decl."), ¶ 5).

Dresses—does not equate to a finding that the ENTRESTO® Trade Dresses are useful (beyond their roles as source identifiers). The Court did not opine that the ENTRESTO® Trade Dresses have "an element of functionality," but instead that medication appearances *can have* an element of functionality where they serve as visual cues for patients and particularly more vulnerable populations. (Op. at 9). MSN's arguments to the contrary should be rejected.

b. *The Court Properly Distinguished* Shire.

MSN's reliance on *Shire US Inc. v. Barr Laboratories, Inc.* is again an attempt to relitigate arguments that this Court has rejected. In its Opinion, the Court recognized the "practical distinctions" between the facts of this case and those of *Shire* and declined to find that *Shire* precluded relief here. (Op. at 9). In drawing these distinctions, the Court considered both parties' briefings on this case, including MSN's "reliance on *Shire*." (*Id.*). It is inappropriate for MSN to use this Motion to revisit those same, rejected arguments.

Moreover, on appeal, MSN cannot expect to prevail on its arguments concerning *Shire*, as MSN's dispute with the Court's Opinion misses the point of the Court's analysis and the case law MSN so heavily emphasizes. The finding of functionality in *Shire* was because Adderall users are particularly sensitive to visual cues and rely on color to distinguish between medication doses when determining which pill to take. *Shire*, 329 F. 3d at 354. Accordingly, regardless of brand, color

coding serves the functional purpose of helping Adderall users identify the proper dose and avoid serious side effects from mistakenly taking the wrong dose based on color cues. *Id.* at 354–55; (*see* Op. at 9).

The pill colors for ENTRESTO® do not serve such a function. As the Court recognized, "ENTRESTO® patients need not distinguish between daily doses, because the patients remove previous ones from their medication cycle after they adjust to a different dosage." (Op. at 9 (citing Nayeri Reb. Decl. ¶¶ 31–32)). Thus, the pill colors for ENTRESTO® distinguish doses of ENTRESTO®—but they are not functional in the way that colors are for Adderall doses.[10]

c. *MSN's Functionality Arguments Regarding the Shape and Size of the Drug Are Similarly Unavailing.*

MSN also argues that the Court "entirely fail[ed] to address the unrebutted evidence that the shape and size of MSN's pills was driven entirely by functional concerns." (*See* Motion at 20). This argument fails for two reasons.

First, the proper inquiry to assess functionality in a trade dress infringement action is whether a *plaintiff's* trade dress is functional—not whether the defendant

[10] MSN's suggestion that "the color coding of a particular [ENTRESTO® pill] confers a substantial degree of clinical functionality for the patient in the titration/adjustment process," because "patients may sometimes need to lower their dose," (Motion at 19 (quoting *Shire*, 329 F.3d at 354)), is disingenuous at best. The Court recognized that ENTRESTO® patients "are taking one type of pill in a day." (Op. at 9). This is not a situation where patients need to choose a dosage from among various options in their possession.

claims their own trade dress is functional. *See* 15 U.S.C. § 1125(a)(3) ("[T]he person who asserts trade dress protection has the burden of providing that the matter sought to be protected is not functional."). MSN cannot show functionality by making self-serving arguments about the supposed functional reasons for its copying.

Second, MSN suggests that each trade dress component should be analyzed independently and if any one component is found to be functional, the trade dress cannot be protected. This is directly contradicted by *Ezaki Glico*, where the Third Circuit acknowledged that "a combination of functional and non-functional features can be protected as trade dress, so long as the non-functional features help make the overall design distinctive and identify its source." 986 F.3d at 258; *see also Am. Greetings Corp. v. Dan-Dee Imports, Inc.*, 807 F.2d 1136, 1143 (3d Cir. 1986) ("Indeed, virtually every product is a combination of functional and non-functional features and a rule denying protection to any combination of features including a functional one would emasculate the law of trade dress infringement."). A court is not confined to examining features independently; rather, it should look at the overall design as a whole. *See, e.g., I.M. Wilson, Inc. v. Otvetstvennostyou "Grichko"*, 614 F. Supp. 3d 114, 145 (E.D. Pa. 2022) ("the shoe design *as a whole*" was non-functional, even though it was comprised of "a particular combination of functional and ornamental features").

d. *The Court Was Not Required to Expressly Address Shimer or His Overreading of FDA Guidance.*

MSN's contention that the Court failed to address the opinions of MSN's expert Martin Shimer, including his opinion that the FDA recommends generic products resemble their branded counterparts, (Motion at 21), is similarly unavailing. Contrary to MSN's suggestion, the Court did acknowledge MSN's argument that it was required to copy Novartis's ENTRESTO® Trade Dresses because of FDA guidance: "An MSN executive also explains that in addition to following FDA guidance that generic tablets should have similar physical characteristics to their branded equivalents, MSN picked colors referencing those used for ENTRESTO® pills so that patients can rely on visual cues to identify what drug and dose they are taking." (Op. at 8 (citing Decl. of Ravikumar Nithiyanandam in Opp'n to Pls.' Motion, ECF No. 1307 ("Nithiyanandam Decl."), ¶¶ 8–10)). The fact that the Court did not specifically mention Shimer when acknowledging this position does not change that the Court fully considered the record and addressed MSN's arguments.

Moreover, Novartis refuted all of Mr. Shimer's contentions. First, Mr. Shimer did not opine that "the FDA recommends that generics be similar in size, shape, and appearance to the reference drug for functional reasons." (Motion at 21). Mr. Shimer referenced FDA guidance that "was intended to promote tablets that are easy to swallow." (Reply at 5). As Novartis explained in its PI briefing, that guidance "does not stand for the proposition that generic pills must be highly similar to their

branded counterparts." (*Id*. (citing Robbins Reb. Decl. ¶¶ 9–14)). Further, Novartis provided evidence that "the FDA . . . has acknowledged that 'trademark laws in the United States do not allow a generic drug to look exactly like other drugs already on the market.'" (*Id.* (quoting ECF No. 4-110 at 2)).

In addition, MSN's assertion that Mr. Shimer "presented undisputed evidence that *every other generic Entresto manufacturer* for whom information is publicly available plans to use a similar color-coding scheme and shape as MSN's product" is incorrect. (Motion at 21). As Novartis explained in its Reply, "generics with distinct shapes from ENTRESTO® have been approved by the FDA." (Reply at 14). Another fact declaration from MSN itself points to multiple approved generics with different colors or shapes. (*See* Nithiyanandam Decl., Ex. 1 (Torrent describes round instead of oval tablets for the 24 mg/26 mg dose; Alembic describes capsule-shaped tablets; and Ascend and Alembic describe light pink, off white, and white instead of violet white for the 24 mg/26 mg dose)).[11]

e. *MSN's Contention of "Dire Anticompetitive Effect" Is Overblown.*

MSN alleges that the Court's ruling will create a "dire anticompetitive effect" because it might force other generic manufacturers to reconfigure the design of their generic ENTRESTO® pills mimicking Novartis's trade dresses. (*See* Motion at

[11] MSN also fails to recognize that copying of trade dress is evidence of secondary meaning. (*See* Brief at 22–23 (listing cases holding the same)).

21). Far from hindering competition, the Order prevents the unlawful and unfair launch of generics that infringe on the ENTRESTO® Trade Dresses. As one of MSN's own declarations illustrates, there are other generics with distinct shapes from ENTRESTO® that have been approved by the FDA. (*See* Reply at 14; Nithiyanandam Decl. ¶ 18 & Ex. 1). This Court's Order will not pose in full or in part any threat to non-infringing generics. In addition, only a minority of generic manufacturers have made information about their tablet trade dress publicly available. As a result, it is possible that a majority of generic manufacturers have opted for different, non-infringing configurations for their drugs. MSN could have done the same but did not.

2. The Court Properly Assessed Secondary Meaning.

MSN's challenge to this Court's finding of secondary meaning is yet another attempt to revisit evidence and legal arguments that it made, or could have made, in its PI opposition briefing. This Court should reject this effort. *See Boynes*, 2023 WL 5221539, at *2; *Int'l Bhd. of Teamsters, Loc. 211*, 2019 WL 9101872, at *2.

The Court held that "Novartis has sufficiently demonstrated secondary meaning" after analyzing the secondary meaning factors that are relevant here: (1) "size of the company, the number of sales, and the number of customers," (Op. at 10); (2) "length and exclusivity of use of the trade dress," (*id.* at 11); and (3) marketing and customer recognition, (*id.* at 11–12). It appropriately found that

Novartis had "met its burden." (*Id.* at 12).

Exclusivity of Use: The Court's finding that Novartis's length and exclusivity of use favored a finding of secondary meaning is consistent with other cases in this Circuit. As Novartis explained in its Reply, "MSN's attempt to undercut Novartis's exclusive use of the ENTRESTO® Trade Dresses by pointing to alleged third-party use within the ***entire*** pharmaceutical market—ranging from treatments for schizophrenia to gout—fails. A comparison to tablets that are not indicated to treat the same condition is an 'irrelevant' comparison of 'apples to oranges.'" (Reply at 8 (quoting *Ciba-Geigy Corp. v. Bolar Pharm. Co.*, 547 F. Supp. 1095, 1106 (D.N.J 1982), *aff'd*, 719 F.2d 56 (3d Cir. 1983))). MSN fails to identify a single pharmaceutical trade dress case supporting a comparison of the ENTRESTO® Trade Dresses with every drug in existence.

Advertising: Similarly, MSN's argument that advertising must call out the ENTRESTO® Trade Dresses to support a finding of secondary meaning, (Motion at 24–26), is unsupported by Third Circuit case law. *See Ciba-Geigy Corp.*, 547 F. Supp. at 1101; (*see also* Op. at 12; Reply at 7; Br. at 21–22). Upon prior consideration of these same arguments from MSN, this Court recognized that Novartis's "expansive marketing campaign" reinforced the source-identifying capacity of the ENTRESTO® Trade Dresses by "routinely featur[ing] the [pills'] physical appearance." (Op. at 11–12). The two in-Circuit cases to which MSN cites

are distinguishable and do not undermine this Court's finding. *See Duraco Prods., Inc. v. Joy Plastic Enters., Ltd.*, 40 F.3d 1431, 1453 (3d Cir. 1994) (advertising did not weigh in favor of secondary meaning where it included only "small depictions of the entire product"); *Buzz Bee Toys, Inc.*, 20 F. Supp. 3d at 500 (advertising factor did not weigh in favor of secondary meaning where there was no evidence of "advertising of the specific trade dress claimed," (internal citation omitted)).

Sales Figures: For the first time, MSN attempts to argue that ENTRESTO®'s large sales volume cannot be probative of secondary meaning "without proof that those sales were generated by the trade dress." (Motion at 27). This is again inaccurate. The Third Circuit has expressly recognized that "[t]he size of a company, its total sales, and the size of its customer base can also be probative of secondary meaning because the jury is entitled to draw the logical inference that '[t]he larger a company and the greater its sales, the greater the number of people who have been exposed to [the] symbol used as a trademark, and the greater the number of people who may associate [that] symbol with a company or source with which they should be familiarized.'" *Parks LLC v. Tyson Foods, Inc*, 863 F.3d 220, 235 (3d Cir. 2017) (citing 2 McCarthy on Trademarks § 15:49).

C. The Court Properly Analyzed the Balance of Hardships and Public Interest.

The Court held that "on balance, a [PI] is warranted" after it acknowledged the potential harm to MSN that such an injunction would cause and "the societal

benefits of affordable alternatives to brand-name drugs." (*See* Op. at 18). It is clear that the Court considered the balance of hardships and public interest and ultimately agreed with Novartis that MSN's injury was "discounted by the fact that the defendant brought that injury upon itself." (*Id.*).

This is distinct from the case cited by MSN, *Fres-co Systems USA, Inc. v. Hawkins*, 690 F. App'x 72 (3d Cir. 2017), where the district court was entirely silent as to the public interest and balance of hardships. *See id.* at 79–80 ("Absent any reasoning on these two factors, we cannot determine whether the District Court reasonably exercised its discretion in granting [plaintiff] injunctive relief."). There was no such silence here; the Court discussed the public interest in affordable alternatives to branded drugs and ultimately found it was outweighed by other considerations. At an appropriate time, approved generics that do not infringe Novartis's trade dress and other rights will be able to enter the market and satisfy any public interest in ENTRESTO® alternatives.

III. MSN Has Provided No New Harm That Supports Staying the PI.

At the PI stage, MSN detailed the harms that it will purportedly face if enjoined. The Court acknowledged those potential harms—including that "[i]t would lose its 'first mover advantage' and face financial, research, and development setbacks"—but found that these harms carried little weight because they were self-inflicted by MSN when it decided to infringe the ENTRESTO® Trade Dresses. (Op.

at 18). These are the exact harms that MSN raises again on this Motion. (*See* Motion at 3, 32 ("A [PI] causing a delay of even a few weeks in MSN's launch…would likely cost MSN its critical first-mover advantage as the first entrant in the market," with "ruinous economic and reputational consequences.")). MSN has provided no reason why the Court should stay the PI that it just granted in deference to harms that it previously rejected as self-imposed.

Moreover, even if these harms did somehow change this Court's prior analysis of the same issue, MSN's Motion would still fail because MSN has not shown that it is likely to succeed on appeal. *See E. Milk Producers Co-op. Ass'n, Inc. v. Lehigh Valley Co-op. Farmers, Inc.*, 448 F. Supp. 471, 475 (E.D. Pa.), *aff'd sub nom.*, 582 F.2d 1273 (3d Cir. 1978) ("[E]ven if irreparable injury is certain to occur, the stay must be denied absent a showing that defendant is likely to succeed on appeal."); *see also Dehainaut v. Cal. Univ. of Pa.*, No. 10-899, 2011 WL 3810132, at *2 (W.D. Pa. Aug. 29, 2011).

IV. Harm to Novartis and the Public Supports Denying MSN's Request.

The Court could deny MSN's Motion without considering the two remaining factors because MSN has failed to show a likelihood of success on appeal or irreparable harm that would justify a stay. *Corp. Synergies Grp.*, 2019 WL 2743791, at *2 (without the requisite showing on the first two factors, "the Court need not consider the remaining factors"). If the Court does reach the question of injury to

Novartis and the public, which is unnecessary, those factors only further support maintaining the PI during the pendency of any appeal.

A. Lifting the PI Would Subject Novartis to the Same Harm That Justified the Court's Order in the First Instance.

The harm to Novartis from the launch of the MSN Drug remains as compelling as it was when the Court granted the PI less than three weeks ago. "'Grounds for irreparable injury include loss of control of reputation, loss of trade, and loss of goodwill' and irreparable harm 'can also be based on the possibility of confusion.'" (Op. at 17 (quoting *S & R Corp. v. Jiffy Lube Intern., Inc.*, 968 F.2d 371, 378 (3d Cir. 1992))). MSN's infringement of the ENTRESTO® Trade Dresses would place the reputation of Novartis in the hands of MSN and make it susceptible to any "quality or safety issues" with the MSN Drug. (*See id*. at 17); *see also* Section II(A)(2) *supra*. MSN could have prevented this harm by choosing a different overall trade dress for its tablets, but it did not. This potential harm to Novartis remains a threat in the face of MSN's continued challenges to Novartis's patent rights and clear expression of its intent to launch the MSN Drug in the event there is any window of opportunity to do so. (*See* Mar. 25, 2025 Letter (ECF No. 36) at 1).

B. Public Interest in Being Free from Confusion Remains Strong.

The public has a strong interest in being free from confusion. This is "[t]he most basic public interest at stake in all Lanham Act cases." *Kos Pharms.*, 369 F.3d at 730. The Court acknowledged "societal benefits of affordable alternatives to

brand-name drugs and laments obstacles to such access" but implicitly recognized these benefits did not outweigh the potential for consumer confusion that would come with allowing the MSN Drug to launch with its infringing trade dress. (*See* Op. at 18); *Nat'l Shooting Sports Found.*, 2023 WL 2344635, at *3 ("Because Defendant has not shown that he is likely to succeed on an appeal, the Court finds that it is in the public interest to continue the injunction.").

V. MSN's Proposed Alternative Relief Could Have the Same Effect as Granting Its Motion in Full.

The alternative relief sought by MSN has no basis in law. There is no basis on which to temporarily stay a properly entered PI when it would allow a change in the status quo. *See HR Staffing Consultants*, 2015 WL 3561618, at *2 ("Far from a mere preservation of some neutral status quo, it would be tantamount to victory for the defendant."). Moreover, MSN's request for a "one-week" stay either will result in prejudice to Novartis or is pointless. To the extent the restraints in both this case and *In re Entresto* are lifted or stayed, such that there is a window of opportunity for MSN to launch, the prejudice to Novartis would be great. If this Court's injunction were to become the only restraint in place, a "one-week administrative stay" would be tantamount to a victory for MSN and incentivize MSN to aggressively launch its products and flood the market with infringing drugs while the Third Circuit considers any motion to stay before it. By contrast, to the extent the restraint in *In re Entresto* remains in place during the pendency of any "one-week" stay in this

case, MSN is no better or worse off as a result of the stay and any such relief is moot.

CONCLUSION

For all the reasons set forth above, Novartis requests that the Court deny MSN's motion for a stay of the PI pending appeal and deny its alternative request for a temporary stay.

Respectfully submitted,

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